

REMARKS

Claims 1, 6, 11, and 16-26 are pending in this application. Non-elected claims 1 and 6 are withdrawn from consideration by the Examiner. By this Amendment, claims 1, 6, and 11 are amended, and claims 25 and 26 are added. Support for the amendments to the claims and the new claims may be found, for example, in the specification at paragraphs [0016] and [0037]. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Personal Interview

The courtesies extended to Applicant's representative by Examiner Anderson at the interview held June 28, are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below, which constitute Applicants' record of the interview.

II. Rejection Under 35 U.S.C. §112

The Office Action rejects claims 11 and 16-24 under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 11 is amended to overcome the rejection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Rejection Under 35 U.S.C. §103

The Office Action rejects claims 11 and 16-24 under 35 U.S.C. §103(a) as having been obvious over Japanese Application Publication No. 61-263917 to Hiroyoshi et al. ("Hiroyoshi") and U.S. Patent No. 6,723,732 to Sugita et al. ("Sugita") in view of Japanese Application Publication No. 10-265373 to Koide et al. ("Koide"), Japanese Application Publication No. 63-203613 to Akira et al. ("Akira"), EP 0 974 350 to Mori et al. ("Mori I") and EP 1 174 132 to Mori et al. ("Mori II"). Applicants respectfully traverse the rejection.

Claim 11 is directed to a method of protecting against cerebral dysfunction, comprising administering to a patient in need of protecting against cerebral dysfunction a percutaneous absorption type pharmaceutical composition that comprises, as an active ingredient, 3-methyl-1-phenyl-2-pyrazolin-5-one in an amount of 0.5 to 10 percent by mass in combination with the recited aqueous base and one or more of talc, lactic acid, isopropanol and polysorbate 80. The applied references would not have rendered obvious the claimed subject matter for at least the following reasons.

The Office Action fails to establish that the applied references disclose the recited active ingredient amount of "0.5 to 10 percent by mass." The Office Action does not establish, and the applied references do not appear to disclose, a percutaneous absorption type pharmaceutical composition comprising 3-methyl-1-phenyl-2-pyrazolin-5-one in an amount of 0.5 to 10 percent by mass. For instance, as acknowledged by the Office Action, Hiroyoshi does not disclose percutaneous absorption of 3-methyl-1-phenyl-2-pyrazolin-5-one. See Office Action at page 4. Thus, Hiroyoshi does not disclose an amount of the recited active ingredient that is effective for protecting against cerebral dysfunction by percutaneous absorption of the active ingredient. Furthermore, there is no evidence of record that the amount of 3-methyl-1-phenyl-2-pyrazolin-5-one suitable for oral, intravenous or intrarectal administration, as disclosed in Hiroyoshi, would have been suitable for percutaneous administration.

Sugita does not disclose percutaneous absorption of a composition comprising 3-methyl-1-phenyl-2-pyrazolin-5-one as an active ingredient. Instead, Sugita discloses a percutaneously administrable preparation comprising 0.05% of cerebral protecting agent Compound (I-1) as the active ingredient. Thus, Sugita fails to disclose the recited active ingredient amount of "0.5 to 10 percent by mass." The remaining applied references, which are only applied for the recited aqueous base and one or more of talc, lactic acid, isopropanol

and polysorbate 80, do not cure the deficiencies of Hiroyoshi and Sugita identified above with respect to claim 11.

As tentatively agreed upon during the interview, for the above reasons, an ordinarily skilled artisan would not have had any motivation to modify the composition of Hiroyoshi to contain the active ingredient in an amount of 0.5 to 10 percent by mass, much less the combination of this amount with the recited aqueous base and one or more of talc, lactic acid, isopropanol and polysorbate 80. At most, the applied references would have motivated an ordinarily skilled artisan to use 0.05% of the recited active ingredient because the only disclosure of the amount of the active ingredient in the applied references is 0.05% of the cerebral protecting agent disclosed in Sugita. Furthermore, while Koide, Mori I and Mori II disclose amounts of the recited aqueous base components, there is no teaching in the applied references that would have motivated an ordinarily skilled artisan to combine these amounts with the specific active ingredient amount of 0.5 to 10 percent by mass.

For at least these reasons, the applied references would not have rendered obvious claim 11 and its dependent claims. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

IV. Rejoinder

Applicants respectfully request rejoinder of non-elected claims 1 and 6. This application is subject to unity of invention practice as set forth in PCT Rule 13. *See* MPEP §1893.03(d). Because claims 1 and 6 share at least one special technical feature with claim 11 and its dependent claims, unity of invention exists between all the claims. Thus, Applicants respectfully request withdrawal of the Restriction Requirement and rejoinder of claims 1 and 6.

V. New Claims

By this Amendment, new claims 25 and 26 are presented. New claims 25 and 26 depend from claim 11 and, thus, distinguish over the applied references for at least the reasons discussed above with respect to claim 11. During the interview, the Examiner tentatively agreed that the subject matter of claims 25 and 26 would not have been obvious over the applied references because they do not provide any motivation to obtain a composition having the recited combination of components. Prompt examination and allowance of new claims 25 and 26 are respectfully requested.

VI. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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